K040359

MAR 1 9 2004

Section 3

510(k) Summary (Summary of Safety and Effectiveness)
HemosIL Special Test Controls Level 1 & 2: Expanded Indications for Use

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

February 12, 2003

Name of the Device:

HemosIL Special Test Controls Level 1 & 2 (Expansion of Indications to for Use)

Classification Name:

864.5425	Multipurpose System for In Vitro Coagulation Studies	Class II
JPA	System, Multipurpose for In Vitro Coagulation Studies	

Identification of predicate device:

K864271 HemosIL Special Test Controls Level 1 & 2

Description of the Device with Expanded Indications for Use:

The intended use to HemosIL Special Test Controls Level 1 & 2 is being expanded with the addition of value assignments for chromogenic Factor VIII tests (Levels 1 and 2) and clotting factor assays (Level 2 only). There are no changes in product formulation or alterations in the fundamental scientific technology introduced with the new value assignments.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL Special Test Controls Level 1 & 2 with the expanded intended use due to the new value assignments is substantially equivalent to the current legally marketed product (K864271).

Summary of Performance Data:

- **Chromogenic Factor VIII:**

Reagent	Instrument	Level	Mean (%) n=32	Within-Run %CV
ELECTRACHROME Factor VIII	ACL 9000	Level 1	67.5	3.30
		Level 2	37.9	3.53

510(k) Summary (Summary of Safety and Effectiveness)
HemosIL Special Test Controls Level 1 & 2: Expanded Indications for Use

Summary of Performance Data (Cont.):

- **Factor Assays (Clotting):**

Reagent	Instrument	Mean (%) n=32	Within-Run %CV
HemosIL Factor II Deficient Plasma	ACL Classic	33.0	4.31
	ACL Futura/ACL Advance	30.8	8.77
	ACL 9000	34.1	3.16
HemosIL Factor V Deficient Plasma	ACL Classic	33.6	2.50
	ACL Futura/ACL Advance	37.1	3.15
	ACL 9000	36.5	2.27
HemosIL Factor VII Deficient Plasma	ACL Classic	30.5	3.09
	ACL Futura/ACL Advance	34.8	6.76
	ACL 9000	33.1	3.53
HemosIL Factor VIII Deficient Plasma	ACL Classic	33.7	5.54
	ACL Futura/ACL Advance	36.1	5.52
	ACL 9000	32.4	6.93
HemosIL Factor IX Deficient Plasma	ACL Classic	34.8	3.23
	ACL Futura/ACL Advance	34.1	10.07
	ACL 9000	34.2	7.45
HemosIL Factor X Deficient Plasma	ACL Classic	31.6	1.65
	ACL Futura/ACL Advance	32.8	2.12
	ACL 9000	34.3	2.13
HemosIL Factor XI Deficient Plasma	ACL Classic	28.5	2.99
	ACL Futura/ACL Advance	30.0	13.24
	ACL 9000	30.2	4.34
HemosIL Factor XII Deficient Plasma	ACL Classic	34.1	7.22
	ACL Futura/ACL Advance	29.7	7.40
	ACL 9000	34.3	2.61

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 9 2004

Mr. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

Re: k040359
Trade/Device Name: HemosIL Special Test Controls Level 1 & 2
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: February 12, 2004
Received: February 13, 2004

Dear Mr. Marble,:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

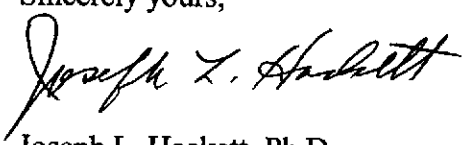
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K040359

Device Name: HemosIL Special Test Controls Level 1 & 2

Indications for Use:

The intended use to HemosIL Special Test Controls Level 1 & 2 is being expanded with the addition of value assignments for chromogenic Factor VIII tests (Levels 1 and 2) and clotting factor assays (Level 2 only). There are no changes in product formulation or alterations in the fundamental scientific technology introduced with the new value assignments.

HemosIL Special Test Controls Level 1 & 2 is labeled:

- For the quality control in the abnormal range of the chromogenic tests (Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Factor VIII) and Free Protein S assay performed on the IL Coagulation Systems.
- For the Quality Control of von Willebrand Factor assay in the normal (Level 1) and abnormal range (Level 2) on the IL Coagulation Systems.
- For the Quality Control of factor assays (clotting) in the abnormal range (Level 2) on the IL Coagulation Systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040359

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)